

AQUADVANTAGE[®] SALMON'S JOURNEY TO MARKET: STILL MAKING HISTORY

Making History is what AquaBounty Technologies has been doing ever since it was created in 1991. Originally named AF Protein (for antifreeze protein, the original focus of research), the Company was created to commercialize a fast-growing Atlantic salmon.

By Dave Conley*

This salmon, created using recombinant DNA technology by a team of scientists based at Memorial University of Newfoundland, in St. John's, NL, Canada, grows to market size (4-5 kg) in about 18 months, instead of the 28-36 months it takes for conventional farmed Atlantic salmon. The basis for the rapid growth is the AquAdvantage gene construct. This single growth hormone gene from

Chinook salmon and promoter sequence from ocean pout, when integrated into the Atlantic salmon genome, enabled the Atlantic salmon to grow continuously to adult size in record time, with the added advantage of using 25% less feed. This product was named AquAdvantage[®] Salmon (AAS).

It turns out that the science of creating the AAS was the easy part, taking only three years (1986-89). De-

veloping and commercializing AAS has taken a journey that is now in its 29th year! For a start-up, that is an extremely long time to go without a market presence and a return on investment.

AquaBounty first approached the U.S. Food and Drug Administration (FDA) in 1993 to find out what the agency would require for AAS to be approved for human consumption. There was no regulatory pathway at



R&D Hatchery in Rollo Bay, PEI

the time, and the Company initiated research which it assumed would be responsive to any eventual requirements. Many years later, but still before any clear regulatory path had been established, AquaBounty decided to create all-female populations of sterile AAS and grow them in land-based aquaculture systems. These all-female populations are created using conventional Atlantic salmon eggs fertilized with the milt from sex-reversed females that carry the AquAdvantage gene construct. Shortly after fertilization, the eggs are subjected to a pressure shock, which makes them triploid (three sets of chromosomes), thus sterile. AquaBounty proposed

this product definition in hopes it would address concerns over the potential release of AAS to the environment.

Progress was slow until 2009, when FDA finally established Guidance 187 for the regulation of genetically engineered animals. Still, it was more than 6 years later when the product was finally approved on November 19, 2015. In Canada, approval came six months later, on May 19, 2016, when AAS was found to be safe to consume by people and livestock.

Backing up a bit, why was AAS approved as a drug? At the time of the application in 1995, there was no

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clear pathway for approval of a transgenic food animal. There were many discussions, stakeholder meetings and other activities intended to identify a regulatory pathway, but there was no consensus. Only in 2009, when a pharmaceutical product (Atryn) produced in the milk of a transgenic goat was about to be approved by FDA, did the regulatory pathway for animals crystallize. In Canada, AAS was approved as a novel food. Both FDA and Health Canada processes were based upon the Codex Alimentarius *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals*.

One would think that with approval from U.S. FDA and Health Canada, the road to commercialization would now be straight-forward. It wasn't. Immediately after the U.S. approval, Senator Murkowski from Alaska, a long-time opponent of AAS, succeeded in having language inserted in the 2016 Omnibus Appropriations Bill that said AAS could not enter commerce until FDA issued labeling guidelines. AAS or any other fish resulting from genetic engineering would require labeling as "genetically modified." Consequently, FDA issued an Import Alert that prevented the Company from importing AAS eggs and fish into the U.S. This was done to comply with the language in the appropriations bill. Since the Company at that time did not have an approved U.S. broodstock or produc-



Interior of R&D Hatchery, Rollo Bay, PEI



Grow-out Tanks, Albany, Indiana




Early Rearing Tanks, Albany, Indiana.

tion facility, eggs or fish would have to be imported from either Canada or Panama, where the Company has a small production farm.

Fast-forward to 2018 and the Company now has two commercial production facilities ready to commence farming AAS. One near Albany, Indiana, the site of a former yellow perch producer, has been fully upgraded to produce 1200 metric tons per year, while another in Rollo Bay, PEI, Canada has been newly constructed to produce 250 metric tons per year.

Both use state-of-the-art recirculating aquaculture system (RAS) technology that recycles more than 95% of the water and both deploy multiple and redundant escape barriers.

Approval of the facilities by the federal regulatory agencies in each country is the last requirement. The approval of the Indiana facility was received from FDA on April 26, 2018. However, the Import Alert issued in 2016 is still in effect and remains the last barrier to commercial AAS production in the U.S. It may be that ap-

proval in Canada comes before the impasse in the U.S. is resolved. But either way, 2018 will be the year that AquaBounty Technologies makes history by commencing the large-scale farming of an innovation that has taken far too long to reach the market. If all goes according to plan, the first commercial harvests in Canada and the U.S. will be in 2020. Until then, the limited production from our Panama R&D facility will be sold in Canada where 4.5 metric tons were sold in a test market in June 2017. Feedback from buyers was very positive and tastings at the recent Aquaculture Canada 2018 conference in Quebec City (Quebec, Canada) and the TasteTECH event during the INVENTURE\$ conference in Calgary (Alberta, Canada) garnered great reviews. We anticipate consumers will be pleasantly surprised when they have the chance to eat our AquAdvantage Salmon. 

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RAS Broodstock Facility, Rollo Bay, PEI

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